

Claim 15 recites, among other features “said exchangeable member providing a cooling means comprising an inlet and an outlet configured to receive and discard a circulating cooling fluid, respectively, for cooling a contact surface of said exchangeable member to be engaged with the skin or mucous membrane and a surface of said transducer, wherein said circulating cooling fluid being in direct fluid communication with said surface of said transducer”. These phrases have support from cancelled claim 17 and the description on page 7, lines 14 to 25.

Claim 29 recites, among other features, “...device a therapeutic ultrasound energy from a transducer, during use, is led; comprising cooling means providing an inlet and an outlet configured to receive and discard a circulating cooling fluid, respectively, for cooling a contact surface of said exchangeable device to be engaged with the skin or mucous membrane, and a surface of said transducer, wherein said circulating cooling fluid being in direct fluid communication with said surface of said transducer, and wherein said exchangeable device forms a heating exchange element between the transducer and the tissue.” This phrase has support in the description on page 7, lines 14 to 25.

According to the features of claims 15 and 29, the exchangeable member provides an inlet and outlet that are configured to provide circulation of a cooling fluid for cooling a contact surface of the exchangeable member. Moreover the circulation of the cooling fluid provides cooling of at least a surface of the transducer, wherein the cooling fluid is in direct fluid communication with the transducer.

It is respectfully submitted that neither Sato (JP 2001-061874) nor Beyer (US 4,448,334 B1) discloses an apparatus according to claim 15 or a device according to claim 29, since the cooling fluid in both Sato and Beyer is separated from the transducer via the bag wall, and accordingly the cooling fluid is not in direct fluid communication with the transducer. Hence,

neither of the two cited documents provide for the possibility to ensure that the transducer surface will be free from contaminations in use while still enabling circulation of the fluid in order to cool the surface of the tissue to which the exchangeable member is applied during treatment.

In Beyer, when replacing the removable bag, there is an evident risk of contaminating the transducer element. If the transducer element becomes contaminated the resulting ultrasonic image created will contain increased noise from backscattering from the contaminations. Accordingly the transducer element has to be cleaned between each use, to enable maintained imaging resolution. According to the present patent application the risk of contaminating the transducer still exists when replacing the exchangeable member, but even if the surface of the transducer gets contaminated during replacement, in use the circulating of cooling fluid will remove the contaminations from the surface, and therefore the resolution in treatment will be remained. Moreover, the exchangeable member according some embodiments of the present invention is configured in such a way that contaminations provided on the surface of the transducer will never come into contact with the external environment being in contact with the tissue of the patient. Accordingly, the transducer head does not need to be sterilized between each use. However a new sterilized exchangeable member will be connected to the apparatus between each use. Neither Beyer nor Sato discloses an exchangeable member according to this solution.

An advantage of the feature of providing the circulating fluid in direct fluid communication with a surface of the transducer, as claimed in claims 15 and 29, is that the surface will be free from contaminations thus removing the risk of backscattering due to dirt

particles in front of the transducer, and moreover the cooling of the transducer surface will be significantly increased.

Furthermore, the feature of providing the circulating fluid in direct fluid communication with a surface of the transducer removes the requirement of prior art to direct the ultrasound through two bag walls, i.e. one bag wall between the transducer and the interior of the bag, and one bag wall between the interior of the bag and the tissue to be treated. According to the present invention, only one membrane will be needed between the transducer and the tissue to be treated. As a consequence, the ultrasound treatment of the tissue present invention will be significantly improved since the back scattering of one bag wall will be eliminated. This means that there will be only two acoustic impedance transitions, instead of four, between the transducer and the tissue to be treated, namely between the space defined by the concave surface 29 and membrane 21, and the membrane 21 and the tissue to be treated. Accordingly, the treatment efficiency will be drastically improved.

Thus, it is respectfully submitted that that independent claims 15 and 29 are not obvious in view of Sato and Beyer for at least the reasons set forth above. Furthermore, it is respectfully submitted that Aida, Ishibashi and MacCarter do not overcome the deficiencies of Sato and Beyer listed above. As a result, dependent claims 16, 18-22 and 30 are not obvious in view of the cited prior art for at least the reasons set forth above.

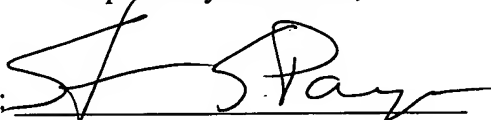
Claims 23-27 stand rejected under 35 USC 102(a) as being anticipated by U.S. Patent No. 6,060,943 to Slayton et al. Claim 28 stands rejected under 35 USC 103(a) as being unpatentable over Slayton et al in view of US patent No. 6,488,626 to Lizzi. Applicant will argue the inapplicability of these rejections to the amended claims.

Claim 23 recites, among other features, "...emitting diagnostic and therapeutic ultrasound energy with a transducer," and "cooling a contact surface of an exchangeable member, to be applied against said tissue, with a circulating cooling fluid, wherein said exchangeable member forms a heating exchange element between said transducer and said tissue; and cooling a surface of said transducer with said circulating cooling fluid, wherein said circulating cooling fluid being in direct fluid communication with said surface of said transducer." This phrase has support in the description on page 7, lines 14 to 25.

It is respectfully submitted that Slayton et al does not disclose, teach or suggest the cooling steps now recited in independent claim 23. Specifically, Slayton et al. does not disclose that the circulation of the cooling fluid provides cooling of at least a surface of the transducer, wherein the cooling fluid is in direct fluid communication with the transducer. Furthermore, Lizzi also does not disclose the cooling steps now recited in claim 23. Thus, claims 23-28 are not anticipated by nor obvious in view of Slayton et al and Lizzi.

In view of the above, it is respectfully submitted that the application is now in condition for allowance. Prompt notice of same is earnestly solicited. If the Examiner believes that a telephone interview may expedite the prosecution of the application, the Examiner is invited to contact the below attorney at the indicated telephone number.

Respectfully submitted,

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